

MAY 31 2011

510(k) Summary

Submitter: Boston Scientific Corporation
One Scimed Place Maple Grove, MN 55311

Contact Person: Mark Murphy
Phone Number: 763-494-2377
Fax Number: 763-494-2222
Date Prepared: May 6, 2011
Device Trade Name: .014 Monorail and OTW PTA Balloon Dilatation Catheters
Common Name: Percutaneous Transluminal Angioplasty Dilatation Catheter
Device Classification: Class II 21 CFR 870.1250 Product Code: LIT

Predicate Devices

Sterling SL Monorail and OTW PTA Balloon Dilatation Catheters and Sterling ES Monorail and OTW PTA Catheters.

Device Description

The .014 PTA Balloon Dilatation Catheters have a coaxial shaft design. The outer lumen is used for inflation of the balloon, and the wire lumen permits the use of guidewires 0.014 in (0.36 mm) to facilitate advancement of the catheter to and through the stenosis to be dilated. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The catheter includes a tapered tip to facilitate advancement of the catheter. The working lengths of the balloon catheter are 90 cm and 150 cm.

Indications for Use

The .014 Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, infrapopliteal, popliteal, renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Substantial Equivalence

The .014 PTA Balloon Dilatation Catheters design, materials, manufacturing process and intended use are substantially equivalent to predicate devices Sterling ES (K080982 and K093636), and Sterling SL Monorail and OTW (K093720) PTA Catheters.

Comparison of Technological Characteristics

The .014 PTA Balloon Dilatation Catheter incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization processes and intended use as those featured in the Boston Scientific predicate devices, Sterling ES PTA Balloon Dilatation Catheter (K080982 and K093636) and Sterling SL PTA Balloon Dilatation Catheter (K093720).

Comparison to Predicate Devices in Materials and Manufacturing

Characteristic	Sterling ES (MR/OTW)	Sterling SL (MR/OTW)
Manifold	Same material. Different colorant. Same design with minor dimensional differences but serving same function	OTW Same material. MR different material. Same design with minor dimensional differences but serving same function
Strain Relief	MR has different material. OTW has same material. Similar designs with serving same function	Same material, different colorant, different designs but serving same function
Catheter Proximal Shaft / Distal Outer	MR different material. OTW similar material. Both designs serving same function	Similar material and design serving same function
Catheter Inner Shaft	Same material, different colorants and serving same function	Similar material, same colorants and serving same function
Bumper Tip	Different material, same colorant but serving same function	Different material, different colorant but serving same function
Balloon	Difference in balloon material and design but serving same function and fundamental technology	Difference in balloon material and design but serving same function and fundamental technology
Balloon Bonding Method	Same bonding method and function	Same bonding method and function
Balloon Forming Process	Same forming method and function	Same forming method and function
Marker Bands	Similar component serving same function	Different component serving same function
Coating	Same coating serving same function	Same coating serving same function
Balloon Protector	Same material and similar design both serving same function.	Same material and similar design both serving same function
Proximal Shaft Outer Diameter	Similar shaft outer diameters	Similar shaft outer diameters

Comparison to Predicate Devices Characteristics

Characteristic	Sterling ES (MR/OTW)	Sterling SL (MR/OTW)
Balloon Diameters	Similar balloon diameter range serving same function	Same balloon diameter range serving same function
Balloon Lengths	Shorter balloon length ranges serving same function	Similar balloon length ranges serving same function
Rated Burst Pressure (RBP)	Similar rated burst pressure	Same rated burst pressure
Catheter Length	Similar catheter length ranges serving same function	Same catheter length ranges serving same function
Recommended Introducer Sheath Compatibility	Similar ranges and compatibilities	Same ranges and compatibilities
Recommended Guidewire	Same compatibility.	Same compatibility
Sterilization Method	Same method.	Same method.
SAL	Same level of assurance	Same level of assurance
Packaging Material and Configuration	Same design and function	Same design and function

Performance Data

Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing.

The following biocompatibility tests were completed on the .014 PTA Balloon Dilatation Catheter:

MEM Elution / Cytotoxicity	Hemolysis / Direct Contact
Guinea Pig Maximization Sensitization	Complement Activation
Intracutaneous Reactivity	Partial Thromboplastin Time
Acute Systemic Toxicity	In Vitro Hemocompatibility
Materials Mediated Rabbit Pyrogen	

Premarket Notification – Special 510(k)
.014 Monorail™ and OTW PTA Balloon Dilatation Catheters

The following in-vitro performance tests were completed for the .014 PTA Balloon Dilatation Catheter:

Balloon Multiple Inflation	Distal Shaft Profile
Balloon Compliance (Distension)	Flexibility and Kink Test
Balloon Diameter at Nominal Pressure	Folded Balloon Crossing Profile
Balloon Length Dimensions (mm)	Particulates Evaluation
Balloon Rated Burst Pressure	Proximal Shaft Profile MR
Bond Tensile	Proximal Shaft Profile OTW
Burst Mode	Radiopacity
Catheter Length Dimensions	Sheath Insertion and Withdrawal Force
	Distal Inner Shaft ID

Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the .014 PTA Balloon Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Boston Scientific Sterling ES PTA Balloon Dilatation Catheter (K080982 and K0936336) and the Sterling SL PTA Balloon Dilatation Catheter (K093720).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

MAY 31 2011

Boston Scientific Corporation
c/o Mr. Mark Murphy
One Scimed Place
Maple Grove, MN 55311-1566

Re: K111295

Trade/Device Name: .014 Monorail and Over-The-Wire PTA Balloon Dilatation Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: LIT, DQY
Dated: May 6, 2011
Received: May 9, 2011

Dear Mr. Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

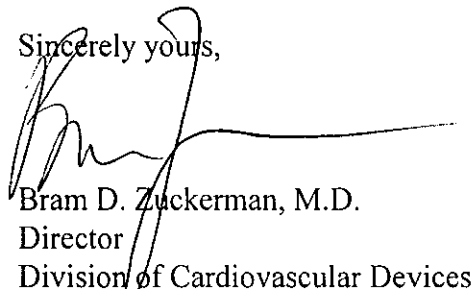
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number
(if known)

K111295

Device Name

.014 MR & OTW PTA Balloon Dilatation Catheters

Indications for
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PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K111295

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter
Use